

BOARD OF REGISTRATION IN PHARMACY PHARMACY BOARD MEETING MINUTES TUESDAY, JANUARY 11, 2005 239 CAUSEWAY STREET, ROOM <u>206</u> BOSTON, MASSACHUSETTS 02114

Present: Karen Ryle, R.Ph., M.S. President, James T. DeVita, R.Ph., Past Pres., Harold Sparr, R.Ph., M.S., Marilyn M. Barron, MSW, Public Member, Joel Berman, R.Ph., Donald Accetta, M.D., M.Ph., Sophia Pasedis, R.Ph., Pharm.D. (arrived 9:20 a.m.), Secretary, William Gouveia, R.Ph., M.S. Absent: Donald Accetta, M.D., M.Ph., George A. Cayer, R.Ph., Pres. Elect and Steven Budish, Public Member.

<u>Staff present:</u> Charles R. Young, R.Ph., Exec. Dir., James Coffey, R.Ph., Assoc. Dir., Susan Manning, Counsel, Leo McKenna, R.Ph., Pharm.D., CQI Surveyor, Jean Pontikas, DHPL Dir., Carolyn Reid, Administrative Asst.

AGENDA ITEMS

- 1. 8:30 a.m. Call To Order – Pres. Karen M. Ryle
- 8:35 a.m.
 Review of Minutes from a previous meeting
 November 09, 2004: Motion/Sparr to approve as submitted. Second/Devita. Motion carried.
 November 23, 2004: Motion/DeVita to approve as amended (page 4.)
 - November 23, 2004: Motion/DeVita to approve as amended (page 4 Second/Berman. The motion carried.
- 3. 8:40 a.m. Report of Offices
 - a) File Review
 - i) Office of Investigations Healthcare Investigators: James C. Emery and Samuel J. Penta

Chuck to review the Walmart matter to invite in the appropriate persons regarding alleged drug losses for Feb. 2005

4, 9:30 a.m.

Report of Offices

- a) Board Counsel Susan Manning (Handout B)
 - i) Pending legal matters
 - ii) Dec. 28 regulations filed effective on Friday, January 14, 2005, when published in MA register (send e-regs plus complete hardcopy when available)

Legislation- overview – a) open meeting law for inv. conference now may be held in closed session – should give rph the option to hold conf in closed session b) fining authority limited to unlicensed practice and or practicing with an expired license (20% of civil fees collected back to trust fund) / Summary suspension analysis – BOP has broad authority – to suspend license authority / we will draft complimentary regulatory language

DeVita recused (exited room)

In the matter of PH-PT-04-083: Thomas Wukawitz, Pharmacy Technician Registration No. 1121. Manning case overview.

Motion/Sparr to adopt the proposed final decision and order by default and revoke the license. Second/Goveia. In support — unanimous. The motion carried. DeVita back in the room post vote.

Berman recused (exited room)

In the matter of Nataria English . Motion/Gouveia to adopt proposed pending final decision and order by defualt and revoke the license. Second/Sparr. Motion carried unanimously less Berman. Berman now back in the room post vote

In the matter of Medi-Rite Pharmacy, Charlton and Drug store closed—sold to CVS- Burke has agreed not to practice until certain terms and conditions are met. Chuck Yoing overview, sell out to cvs, records and medications to we have possession of the pharmacists license.

Drug Store: Motion/Sparr to close the complaint without further action being that pharmacy is transferred. Second/Pasedis. The motion carried.

manning overview — concerns regarding pyschological issues (medical and psych evaluation) and — license is now expired (license on hold now). Susan In the matter of PH-03-093 /Albert Chow, R.Ph., — notice of appeal to Superior Judicial Court.

Motion/Sparr to exit adjudicatory session. Second/Pasedis. Motion carried. Sophia would like case numbers for 2004 regarding complaint status:

5. 9:50 a.m.

Report of Committees

- a) Strategic Planning / Grid Management (Handout C)
 - i) Regulation update Board counsel
 - ii) Transfer of New Rx Final Draft Policy to review
 - iii) Continuing Education Committee review of CE programs
 - iv) DHPL Strategic Planning Initiative James D. Coffey

6. 10:10 a.m.

New Business for discussion (Handout D)

- a) Request for extension of Board-approved pharmacy technician assessment examination MPHA Motion/Sparr to approve exam for June 30, 2005 must develop new examination. Second/DeVita. The motion carried.
- b) Request for 2004 continuing education waiver for Registrant, Daniel W. Sullivan,

R.Ph., (Lic. No. 14313) need proof of 2003 ce's, do 30 ce's motion/waive 2004 upon receipt of proof he did 2003. Second/Pasedis. The motion carried.

- c) Request for 2004 continuing education waiver for Registrant, David H. Jenkins, R.Ph. (Lic. No. 17062) Motion/Ryle do 30 for 2005. Second/Gouveia. The motion carried.
- d) Request for 2004 continuing education waiver for Registrant, Jyoti Shah (Lic. No. 23551). approve/Sparr. Second/. The motion carried.
- e) Motion/Sparr for Ryle to NABP delegate. Second/PASEDIS. Motion carried. Motion/Sparr for DeVita to serve as the alternate delegate. Second/Pasedis. The motion carried.

7. 10:20 a.m.

Old Business (Handout E)

a) DECISION ITEM: Request for Advisory Opinion Request for an Advisory Opinion regarding a proposed application for a New Pharmacy Department

In the matter of Louis and Clark Pharmacy, to be located at MassMutual, 1295 State Street, Springfield, Massachusetts. The applicant was represented by VP of Operations, Tracey Applebee-Cole, R.Ph. (Lic. No. 21632 exp. 12/31/2006).

Applicant met with the Board on December 14, 2004, to discuss the merits of an advisory opinion request regarding waiver consideration of 247 CMR 9.01(15) as such related to the approval of a pharmacy department to be located on the premises of the MassMutual Financial Group.

Young overview – full retail pharmacy, is open to the public but you have DeVita concern that the public would need to know someone at MM to gain access to the proposed pharmacy.

Motion/Sparr to deny a full retail license unless the applicant can demonstrate clear and unrestricted access to pharmacy for the public. Second/Ryle. In support all except Gouveia. Opposed-Gouveia. The motion carried.

8. 10:30 a.m.

Application for a New Pharmacy / Pharmacy Department (Handout F) In the matter of Neighborhood Pharmacy, 27 Water Street, Wakefield, Massachusetts 01880. The applicant is represented by proposed Manager of Record, Thomas A. Putney, R.Ph. (Lic. No. 22970 exp. 12/31/2006), Chairman, William D. Haylon, and Pharmaceutical Strategies President, Michael J. Tocco, R.Ph., M.Ed.

The purpose of the meeting is to discuss the merits of an application for licensure as a new pharmacy.

The pharmacy will be open to the general public.

Putney ce complaint

Putney says a full service pharmacy to meet all patient. To compliment an existing diabetes otc supply operation. Will engage in some mail order. No other pharmacy locations.

CDE available for patients. Signs will be posted along with hours and manager of record (no waivers requested). The company is a wholly owned subsidiary. Will accept any insurance. Pharmacy on the 2nd floor of the building with handicapp access, consultation area room" available, beeper call for after hours service, will have voice mail message in effect post closing for emergency needs of patients particuliary from Sat at 12 pm to Monday morning.

Do any officers of corporation have rx privelages - no, a nurse practitioner but no ownership of company stock.

Motion/DeVita approve application subject to compliant inspection. Second/Berman. The motion carried

9. 11:00 a.m.

Request for Waiver (Handout G) In the matter of Stop & Shop Pharmacy #003 (Permit No. 2330), 235 Old Connecticut Path, Framingham, MA 01701

The purpose of the meeting is to discuss a waiver request for approval specific to 247 CMR 9.01 (17) wherein a proposal specifies that physician samples would be provided to Stop & Shop #003 by Dr. Paul Hart c/o his Sudbury Clinic for subsequent dispensing to his indigent patients. Stop & Shop Pharmacy will be represented by Senior Manager of Pharmacy Support Services, Gregg Jones, R.Ph.

Recused: Berman

Jones: started similar pilot program on or abou 5 years ago in Worcester, unique 3rd party situation set up, less than 50 chemical entities availbale, ss keeps track of inventory and advises hart on an on going basis, monitoring exp. Dates, ss gives hart back the expired medications,

Sudbury: Congegation Beth El in Sudbury, dr. hart uses a rx blanc, ss uses sample original packaging,

Young- must e licensed by pilot project -99 pdma revisions- samples in retail pharmacy assumed to be "State approved pilot project" all pursuant to rx, appt recordkeeping and dispensed at no charge

KR- would li

Motion/Sparr to extend pilot program authorization status to Stop & Shop Pharmacy #003, 235 Old Connecticut Path, Framingham contingent upon FDA approval. Second/Pasedis. The motion carried.

10, 11:30 a.m.

Presentation

Leo A. McKenna, R.Ph., Pharm.D., Board Quality Assurance Coordinator provided an overview of the January 06, 2005, Massachusetts Coalition for the Prevention of Medical Errors educational program related to Failure Modes and Effects Analysis (FMEA) and Proactive Risk Assessment. A handout was distributed to the Board for reference.

RCA is post incident. FMEA is pre-incident. Karen says please include new related terminology of FMEA for future CE programs (an oveview 3 slides or so). Patientsafety.com is a quality website reference for FMEA materials

11. Informational Items (FYI's) / (Handout H)

- 2005 Board of Pharmacy Meeting Calendar Motion/Ryle to **change** the April 19th Board meeting date to April 27th, 2005. Second/DeVita. Motion carried.
- Implementation of New Mileage Reimbursement Rate, effective January 01, 2005
- December 2004 Board of Pharmacy Newsletter
- FDA Bulletins regarding Kepivance and Celebrex Pharmacy
- Public Hospitals: The Healthcare Safety Net of the 21st Century January 14,
 2005 Forum, Blue Cross Blue Shield of MA Corp. Headquarters, Boston. Karen likely will attend this meeting.
- ACPE news release- Recognition of CCAPP Accreditation Decisions not extended beyond June 30, 2004
- NADDI New England Training Conference March 21-22, 2005 in Meredith, NH
- NABP correspondence regarding Wholesale Distributor Model Rules and Regulatory Update related survey completed by Chuck Young.
- NABP correspondence regarding Telemedicine Company and Online Pharmacy
- NABP Testimony on Electronic Signatures
- NABP notice regarding Information for FDA Contact
- 12. 12:00 p.m. Motion/Sparr to Adjourn. Second/Berman. The motion carried. Meeting adjourned.

Board okay to include ph tech certification req. as future agenda item.